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10/576,756	04/21/2006	Keiji Shigesada	Q94144	6027

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EXAMINER	
DOE, SHANTA G	

ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
05/27/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/576,756	SHIGESADA ET AL.	
	Examiner	Art Unit	
	SHANTA G. DOE	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *6-11 and 18-25* is/are allowed.

6)☒ Claim(s) *1-5 and 12-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment (addition of claims 24 &25) filed on 03/22/2010 has been acknowledged and entered by the examiner.

Response to Arguments

2. Applicant's arguments filed 03/22/2010 have been fully considered but they are not persuasive. The applicant's argument that both the Moring and Mori references fail to disclose the feature of the cartridge of the present invention described in claim 1 stating the step of inserting a bottom member and nucleic acid-adsorptive porous membrane… in the structure of the cartridge of claim 1, the cylindrical part and the bottom member are formed integrally sandwiching and holding the nucleic acid-adsorptive porous membrane through the injection molding so as not to be separate was not found persuasive because the prior discloses all of the limitations as is claimed in the product part of claim 1. Claim 1 is a product-by process claim and according to MPEP (2113) a product-by-process claim is not limited to the manipulations of the recited steps only the structure of the product, the determination of the patentability is based on the product itself. Additionally, the patentability of a product does not depend on its method of production. In the product of claim 1 the applicant did not claim that the cylindrical part and the bottom member are formed integrally sandwiching and holding the nucleic acid-adsorptive porous membrane through the injection molding so as not to be separate. Hence the product as claimed in claim 1 is disclosed by the prior art.

Furthermore, the applicant's argument that the prior art fails to disclose that a closer portion of the nucleic acid-adsorptive porous membrane to the bottom part opening is made more displaced towards the discharge part during use was not found persuasive because the applicant is arguing an intended use of the claimed device which does not structurally limit the device or structurally distinguish it from what is being thought in the prior art.

Double Patenting

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

4. Claims 24 and 25 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 3 and 4 respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 12-17, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Moring et al (US 6,159,368).

Regarding claim 1, Moring discloses a cartridge ((12) called minicolumn of a column plate) for nucleic acid separation and purification which comprises: a cylindrical main body formed of a cylindrical part (12) and a bottom part having an opening; and a nucleic acid-adsorptive porous membrane (8) held on the bottom part, a rim part of the nucleic acid-adsorptive porous membrane being held by a molding material forming the cylindrical part of the cylindrical main body (col. 12 lines 6-7 states that the device is made by injection molding and col. 16 lines 35-42 states that filter element is compressed between the shoulder and rim 16a in a manner effective to secure the filter element in place and to press the circumferential side edge against the inner surface of the column) which cartridge is produced by: inserting a bottom member and the nucleic acid-adsorptive porous membrane into a cavity of an injection molding die wherein the nucleic acid-adsorptive porous membrane is placed in the bottom member providing the bottom part which is one of two parts that sandwich and hold the nucleic acid-adsorptive porous membrane; and injecting the molding material into the cavity to form the

cylindrical part of the cylindrical main body wherein a portion forming the cylindrical part which is the other of the two parts that sandwich and hold the nucleic acid-adsorptive porous membrane is integrated with the bottom member while the nucleic acid-adsorptive porous membrane is sandwiched and held between the cylindrical part and the bottom part (see abs, fig 4-6, col.4 lines 12- 15, 47-49, 65- col. 5 line 5; col. 6 lines 15-20 ,col. 12 lines 6-7; col. 15 – col. 17).

Regarding claim 2, Moring discloses the cartridge for nucleic acid separation and purification according to claim 1, wherein the bottom member further comprises a cylindrical discharge part (see fig 4&5. the end part of funnel shaped piece of (16)) communicating with the opening of the bottom part.

Regarding claims 3 and 24, Moring discloses the cartridge for nucleic acid separation and purification according to claim 1, wherein the rim part of the nucleic acid-adsorptive porous membrane is held and compressed by injection pressure of the molding material forming the cylindrical part of the cylindrical main body (see fig -6, col. 12 lines 6-7, and col. 16 lines 35-42).

Regarding claims 4 and 25, discloses the cartridge for nucleic acid separation and purification according to claim 3, wherein the rim part of the nucleic acid-adsorptive porous membrane is compressed until voids in the membrane disappear (see fig 4-6; col. 16 lines 35-56).

Regarding claim 12, Moring discloses a cartridge for nucleic acid separation and purification comprising a cylindrical body with a first opening (top opening in 12) and a second opening (opening covered by filter 8a, see fig 3 -6) and having a nucleic acid-adsorptive porous membrane (filter 8) held in the cylindrical body, in which separation and purification of nucleic acid are conducted by passing a sample solution containing nucleic acid by pressurized gas from the first opening to the second opening to allow the nucleic acid to be adsorbed to the nucleic acid-adsorptive porous membrane, wherein: the cylindrical body comprises: a cylindrical main body having a bottom part supporting the nucleic acid-adsorptive porous membrane (8); and a discharge part (16 c) connecting a bottom part opening formed in the bottom part and the second opening; the bottom part has a bottom face (16a) and a plurality of protrusions (58a, 58b &58c) formed on the bottom face; at least a part of a top part of each protrusion supports the nucleic acid-adsorptive porous membrane (see fig 6); and a closer portion of the nucleic acid-adsorptive porous membrane to the bottom part opening is made more displaced towards the discharge part during use (see abs, fig 3-6, col.4 lines 12-15, 47-49, 65-col. 5 line 5; col. 6 lines 15-20, col. 12 lines 6-7; col. 15-col. 17).

Regarding claim 13, Moring discloses the cartridge for nucleic acid separation and purification according to claim 12, wherein the plurality of protrusions (58a, 58b &58c) are a plurality of ribs radially extending from the bottom part opening (see fig 6).

Regarding claim 14, Moring discloses the cartridge for nucleic acid separation and purification according to claim 13, wherein the top part of the rib is rounded (see fig 6 (58a, 58b &58c)).

Regarding 15, Moring discloses the cartridge for nucleic acid separation and purification according to claim 12, wherein the bottom face has a slope so that a closer portion of the bottom face to the bottom part opening is displaced more towards the discharge part (16c) (see fig 4 (16b)).

Regarding claim 16, Moring discloses the cartridge for nucleic acid separation and purification according to claim 12, wherein edges and corners present in an inner surface of the cartridge for nucleic acid separation and purification are rounded (see fig 6).

Regarding claim 17, Moring discloses the cartridge for nucleic acid separation and purification according to claim 12, wherein the nucleic acid-adsorptive porous membrane is held with a rim part thereof being compressed (col. 16 lines 35-42).

3. Claims 1 & 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Mori et al (US 2003/0170664).

Regarding claim 1, Mori discloses a cartridge (1) for nucleic acid separation and purification which comprises: a cylindrical main body formed of a cylindrical part (12) and a bottom part having an opening (101); and a nucleic acid-adsorptive porous membrane (30) held on the bottom part, a rim part of the nucleic acid-adsorptive porous membrane being held by a molding material forming the cylindrical part of the cylindrical main body which cartridge is produced by: inserting a bottom member and the nucleic acid-adsorptive porous membrane into a cavity of an injection molding die wherein the nucleic acid-adsorptive porous membrane is placed in the bottom member providing the bottom part which is one of two parts that sandwich and hold the nucleic acid-adsorptive porous membrane; and injecting the molding material into the cavity to form the cylindrical part of the cylindrical main body wherein a portion forming the cylindrical part which is the other of the two parts that sandwich and hold the nucleic acid-adsorptive porous membrane is integrated with the bottom member while the nucleic acid-adsorptive porous membrane is sandwiched and held between the cylindrical part and the bottom part (see abs, fig 1 & 2, [0009], [0017]-[0018], [0031, [0037],[0055],[0069],[0072]-[0073],[0090], [0092]-[0093]).

Regarding claim 2, Moring discloses the cartridge for nucleic acid separation and purification according to claim 1, wherein the bottom member further comprises a cylindrical discharge part (101) communicating with the opening of the bottom part (see fig 2).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moring et. al (US 6,159,368).

Regarding claim 5, Moring discloses the cartridge for nucleic acid separation and purification according to claim 3, wherein the rim part of the nucleic acid-adsorptive porous membrane is compressed. Moring fails to disclose that the membrane is compressed to a thickness of 10% to 70% of an initial thickness.

However, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the membrane be compressed to a thickness of 10 -70 % of an initial thickness, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art.

Allowable Subject Matter

8. Claims 6-11 and 18-23 are allowed.

Regarding claim 6 and its dependent claim, the prior art alone or in combination fails to discloses a method for producing a cartridge for nucleic acid separation and purification: the method comprising a step of placing the nucleic acid absorptive porous membrane on the bottom part provided in the bottom member and placing the bottom member and the membrane in a cavity of an infection molding die; a step of pressing a core pin to the membrane while holding the membrane with a rim part of the membrane protruding from the periphery of and end face of the core pin and closing the injection molding die; a step of injecting a molding material into the cavity forming the cylindrical part of the

cylindrical main body and at the same time sandwiching and holding the rim part of the membrane between the molding material and the bottom part and step of removing a casting from the injection molding die.

Regarding claims 18-23, the prior art alone or in combination fails to disclose a cartridge for nucleic acid separation and purification comprising a cylindrical body which comprises a cylindrical main body having a bottom part supporting a nucleic acid-adsorptive porous membrane, and a discharge part connecting the bottom part opening formed in the bottom part and the second opening and a thickness of a part forming the second opening of the discharge part is 0.2mm or more.

The closest prior art to the applicant invention claimed in claims 6-11 and 18-23 is Moring et. al (US 6,159,368).

Regarding claims 6-11, the Moring reference discloses a cartridge for nucleic acid separation and purification where the cartridge comprises a cylindrical main body formed of a cylindrical part and a bottom part having an opening and a nucleic acid adsorptive porous membrane held on the bottom part wherein the device is made by injection molding (see Moring abs, fig 4-6, col.4 lines 12- 15, 47-49, 65- col. 5 line 5; col. 6 lines 15-20 ,col. 12 lines 6-7; col. 15 – col. 17. However, the reference fails to disclose the specifics of the method by which the device is made and hence the reference fails to disclose the steps of the method as is claimed by the applicant in claim 6.

Regarding claims 18- 23, the Moring reference discloses a cartridge for nucleic acid separation and purification where the cartridge comprises a cylindrical main body formed of a cylindrical part and a bottom part having an opening and a nucleic acid adsorptive porous membrane held on the bottom part wherein the device is made by injection molding, However, the reference fails to disclose that the thickness of a part forming the second opening of the of the discharge part is 0.2 mm or more.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANTA G. DOE whose telephone number is (571)270-3152. The examiner can normally be reached on Mon-Fri 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GSD

/Walter D. Griffin/
Supervisory Patent Examiner, Art Unit 1797